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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,729	12/21/2001	Jaap M. Middeldorp	9250-13DVCTDV	6359
20792	7590	04/06/2004	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

### Application No.

10/036,729

### Applicant(s)

MIDDELDORP ET AL.

### Examiner

Young J. Kim

### Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-9, 23 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 and 9 is/are allowed.
- 6) ☒ Claim(s) 7, 8, 23 and 25-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action responds the Amendment received on January 16, 2004.

#### ***Preliminary Remark***

The Office acknowledges the cancellation of claims 1-5, 10-22, and 24 and the addition of claims 30 and 31 in the Amendment received on January 16, 2004.

#### ***Claim Rejections - 35 USC § 101***

The rejection of claims 6-8 under 35 U.S.C. 101 because the claimed invention is directed non-statutory subject matter, made in the Office Action mailed on August 8, 2003, is withdrawn in view of the Amendment received on January 16, 2004, amending the claims.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 6, 9, 23, and 25-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on August 8, 2003 is withdrawn in view of the Amendment received on January 16, 2004, amending the claims.

#### ***Rejections Necessitated by Amendment***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 7, 8, 25, 30, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 8 are indefinite because it is unclear whether the “subsequence” encodes an Epstein-Barr Virus peptide that is immunochemically reactive with antibodies to the Epstein-Barr Virus or an isolated nucleic acid sequence comprising the “subsequence” encodes an Epstein-Barr Virus peptide that is immunochemically reactive with antibodies to the Epstein-Barr Virus. For the purpose of prosecution, the latter interpretation is assumed as the specification does not have any definition regarding a nucleic acid subsequence encoding the EBV. Amending the claims to recite the phrase, “or a subsequence thereof, wherein said subsequence encodes an Epstein-Barr Virus peptide that is immunochemically reactive with antibodies to the Epstein-Barr Virus,” would distinctly claim the subject matter.

Claims 25, 30, and 31 are indefinite for the recitation of the phrase, “reagent(s) for the amplification of Epstein-Barr Virus nucleic acid sequence with the nucleic acid sequence(s) in (a),” because element (a) of the kit is a set of primers, derived from a nucleic acid. Therefore, it is confusing whether the reagents of the amplification of element (b) amplifies the EBV nucleic acid sequence with a set of primers or another “nucleic acid sequence(s).”

#### ***Claim Rejections - 35 USC § 102***

The rejection of claims 7, 8, and 26-29 under 35 U.S.C. 102(b) as being anticipated by Ambinder et al. (Abstracts from Annual Meeting American Society of Microbiology, 1989, 89 Meet., 111), made in the Office Action mailed on August 8, 2003 is maintained for the reasons of record. New claims 30 and 31 are also maintained in the present rejection as the

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Applicants' arguments presented in the Amendment received on January 15, 2004 have been fully considered but they are not found persuasive for the reasons below. Applicants' arguments are addressed in the same order presented.

Applicants traverse the rejection because the newly amended claim, wherein the phrase, "comprising SEQ ID NO: [] or a subsequence thereof encoding an Epstein-Barr Virus peptide that is immunochemically reactive with antibodies to the Epstein-Barr Virus" (page 9, bottom paragraph, underline in original), stating that the claimed "fragments" encode an immunoreactive peptide and are thus clearly longer than one nucleotide in length (page 9, bottom paragraph). Applicants are advised that the interpretation of the claim as discussed above does not require the fragments to encode the Epstein-Barr Virus peptide that is immunochemically reactive with antibodies to the Epstein-Barr Virus. Therefore, claims still embrace an isolated nucleic acid comprising a subsequence (or a single nucleotide) in common to the polynucleotide comprising the claimed SEQ ID Numbers, rendering the claims anticipated by Ambinder et al.

Applicants also traverse the rejection stating that the polynucleotide disclosed by Ambinder et al. do, "not encode peptides that are immunochemically reactive with antibodies to the Epstein-Barr Virus," (page 9, Response) as already set forth above, rendering the claims anticipated.

With regard to claims 30 and 31, Ambinder et al. disclose a method of detecting EBV sequences in clinical specimen by amplification method involving primers. A plasmid containing EBV is disclosed as being amplified, which evidences the presence of a nucleic acid encoding EBV with at least one common nucleotide with that of SEQ ID Number 1 or 3, rendering the claims anticipated.

***Conclusion***

Claims 7, 8, 23, and 25-31 are rejected. Claims 6 and 9 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

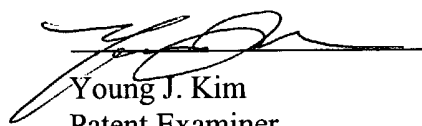
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993).

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(see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (517) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0507.



Young J. Kim  
Patent Examiner  
Art Unit 1637  
4/5/04



KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

4/5/04